K090478 (pg 1/1)

MAR 2 6 2009

510(k) SUMMARY

NAME OF FIRM:	Advanced Orthopaedic Solutions, Inc. 386 Beech Ave., Unit B6 Torrance, CA 90501 310.533.9966 FAX 310.533.9876
510(k) CONTACT PERSON:	Paul Doner, Vice President Operations
TRADE NAME:	AOS Proximal Humeral Nail
COMMON NAME:	Intramedullary Fixation Rod
CLASSIFICATION:	888.3020 Intramedullary Fixation Rod
DEVICE CODE:	HSB
SUBSTANTIALLY EQUIVALENT DEVICE:	AOS Humeral Nail (K050241, Cleared March 14, 2005)

INTENDED USE:

The AOS Proximal Humeral Nail is intended to treat stable and unstable proximal fractures of the humerus including two and three, and in some cases, four part humerus fractures.

DEVICE DESCRIPTION AND SUBSTANTIAL EQUIVALENCE RATIONALES:

The AOS Proximal Humeral Nail is a titanium humeral intramedullary nail that is designed to enter the humerus through the greater tuberosity. It consists of an intramedullary nail, proximal and distal locking screws, and an end cap.

The AOS Proximal Humeral Nail is a cannulated nail with a 6° proximal bend and a proximal diameter of 10mm. The Humeral Nail is produced in a 15cm length with a distal diameter of 8mm. The proximal end of the nail has six holes which accept the 5.0mm cancellous screw. The distal end of the nail contains four cross locking holes which are designed to accept a 3.5mm cortical screw. The proximal end of the nail is threaded to accept an end cap.

The AOS Proximal Humeral Nail was shown to be substantially equivalent to the AOS Humeral Nail. The AOS Proximal Humeral Nail was shown to be substantially equivalent in design, materials and intended use to the device listed below. Once assembled the geometry of the AOS nail and the predicate devices are virtually identical. Additionally, mechanical testing showed that the device is substantially equivalent.

AOS Humeral Nail	K050241, Cleared March 14, 2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2009

Advanced Orthopaedics Solutions, Inc.
% Mr. Paul Doner
386 Beech Avenue, Unit B6
Torrance, California 90501

Re: K090478
Trade/Device Name: AOS Proximal Humeral Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: II
Product Code: HSB
Dated: February 19, 2009
Received: February 24, 2009

Dear Mr. Doner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K090478 (ps 1/1)

Device Name: AOS Humeral Nail

Indications for Use:

The AOS Humeral Nail is intended to treat stable and unstable proximal fractures of the humerus including two and three, and in some cases, four part humerus fractures.

Prescription Use: X (Part 21 CFR 801 Subpart D) and /or Over the Counter Use: _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090478